

REMARKS

FORMAL MATTERS:

Claims 31, 33-56 are pending after entry of the amendments set forth herein.

Claims 32 is canceled without prejudice.

Claims 31, 33, 35 and 50 are amended.

The amendments to claim 31 are supported within previously pending, now canceled claim 32.

The amendments to claims 33, 35 and 50 are formal in nature and are made in order to change the dependencies of these claims in view of the cancellation of claim 32 and to provide antecedent basis for terms within claim 50.

No new matter is added.

OBJECTION TO THE DRAWINGS AND SPECIFICATION

In response to the objections to the drawings applicants have submitted a complete new set of formal drawings which are believed to be in proper form in accordance with Patent Office rules. No new matter has been added.

The amendments to the specification are done in order to correct clerical errors. No new matter has been added.

REJECTIONS UNDER §112, ¶2

Claim 50 was rejected under 35 U.S.C. §112, second paragraph. The objection was correct. Accordingly, the dependency of claim 50 has been changed and this change is believed to provide a proper antecedent basis for all of the components recited within claim 50. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

PRIOR ART IN GENERAL

There are three pending independent claims which are claims 31, 41 and 56. Each of these claims include specific features which are distinguishable from the prior art references. An effort has been made to break away the distinguishing features in each of the independent claims. However, overall the prior art is not teaching towards a needleless injection device which includes the safety device configurations as disclosed and claimed by applicants. Applicants have found that needleless

injector devices require special consideration regarding the inclusion of safety mechanisms to prevent accidental firing of the device. With conventional needle delivery devices the need for some safety in terms of preventing a needle prick is obvious to all users. However, the need for a safety mechanism in connection with a needle free delivery device is far less obvious. Further, in connection with a conventional syringe which uses a needle it is always clear to the user when the device has been used. Such is not the case with a needleless delivery device. Applicants' mechanisms make it possible to provide for the prevention of accidentally firing the needle-free delivery device and provide for a device which after being fired can be recognized as having been used. Specific claim language distinguishing the invention from each of the cited references is provided below.

REJECTIONS UNDER §102

Claims 31-56 were rejected under 35 U.S.C. §102 as anticipated by Castellano. The rejection is traversed as applied and as it might be applied to the presently pending claims.

Castellano re Claim 31

In support of the rejection reference has been made to the safety clip 5026 as referenced in the specification at col. 22, line 34 and shown in Figure 28A. It appears as though the rejection is attempting to show that the component of 5026 is equivalent to the "safety mechanism" as recited within claim 31. However, if the clip 5026 of Castellano is the safety mechanism then Castellano does not disclose and actuator mechanism as recited within amended claim 31. The actuator mechanism moves the safety mechanism from its first configuration to a second configuration. Thus, for this reason alone Castellano does not anticipate amended claim 31.

Castellano re Claim 41

Claim 41 is also an independent claim which has been rejected as anticipated by Castellano. However, claim 41 includes a "break-off tip". The break-off tip encloses the cartridge orifice prior to being broken off. Castellano does disclose a protective cap 5046 in Figure 14. The only portion of the Castellano patent referring to the cap 5026 reads as follows:

In addition, a **protective cap 5046** that covers the orifice 5006 of the ampoule can be a hard material, such as plastic, metal or the like, or a soft generally compliant rubber material. The **protective**

cap 5046 is generally snapped onto the end of the ampoule 5004. However, alternative embodiments may utilize threads. Further, the safety clip 5026 can be a hard material, such as plastic, metal or the like, or a soft generally compliant rubber material, if it can resist movement of the actuator button 5029 towards the ampoule 5004.

To use the needle-less injector device 5000, the user removes the **protective cap 5046** that covers the orifice 5006 of the ampoule 5004. The user also removes the safety clip 5026. **(Bold added)**

The cap 5046 of Castellano is not a break-off tip. By using a break-off tip the tip cannot be replaced once broken off and a user will readily recognize that the device has been discharged. Such is not the case with the Castellano device where the cap can be taken off and placed back on giving the appearance that the device has not been discharged. Such is a non-obvious difference between the invention claimed in claim 41 and Castellano. In view of such reconsideration and withdrawal of the rejection is respectfully requested.

Castellano re Claim 56

The remaining independent claim is claim 56. Claim 56 also includes the casing which is comprised of a break-away part. As indicated above Castellano does not disclose such a break-away part. In view of such Castellano does not anticipate any of the independent claims and therefore, by definition, cannot anticipate any of the dependent claims. Thus, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 31-56 were rejected under 35 U.S.C. §102 as anticipated by Haar et al. The rejection is traversed as applied and as it might be applied to the present pending claims.

Haar et al. do not teach a safety mechanism and an actuator mechanism as claimed specifically wherein the actuator mechanism comprises a portion extending inside the casing which portions is accessible to a user and which when the portion is moved by the user the movement brings a safety

mechanism into its second position. This is specifically claimed within amended claim 31 and not taught within Haar et al.

With respect to independent claims 41 and 56 it is pointed out that Haar et al. do not disclose any break-off component of any type.

In support of the rejection reference is made to the ball-latch 39 referred to at paragraph [0069]. However, this is a standard trigger mechanism. Haar et al. do disclose a removable cap 44 which is indicated as serving for locking outer housing 46 in position with respect to inner housing 49 to prevent accidental release of trigger 36. The cap 44 is referred to in paragraph [0071] and shown in Figure 7. Based on the figure, it appears as though the cap 44 screws onto the housing 49 and is not a break-off cap. Thus, Haar et al. do not anticipate independent claims 31 or 56 which include the break-off portion.

Assuming the rejection intends to refer to the cap 44 as the safety mechanism then Haar et al. do not teach an actuator mechanism as claimed in claim 31 which moves the safety mechanism from the first configuration to a second configuration. Thus, the independent claim 31 is not anticipated by Haar et al.

As regards applicants' invention there is a non-obvious benefit of having a break-off tip as opposed to a screw off tip in that the screw off tip can be replaced causing the device to appear unused. Further, there is a non-obvious benefit to having an actuator mechanism which moves the safety mechanism from the first configuration into a second configuration, particularly when the actuator mechanism includes a portion which extends outside the casing as claimed within amended claim 31. Such is clearly not taught by Haar et al.

REJECTION OVER SCHIFF ET AL.

Claim 31 was rejected under 35 U.S.C. §102 as anticipated by Schiff et al. The rejection is traversed as applied and as it might be applied to the presently pending claims. The rejection was not applied against dependent claim 32. The limitations of dependent claim 32 are now incorporated into independent claim 31 thereby rendering the rejection moot.

Claims 41 and 56 were not rejected over Schiff et al. and none of the claims were rejected as being obvious over Schiff et al. However, as pointed out above the prior art does not teach the general concepts as taught within any of the independent claims. The different configurations of the safety mechanisms as claimed by applicants are unobvious in view of Schiff et al. and as such are patentable over Schiff et al.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number ZGNX-115.

Respectfully submitted,
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